

## **REMARKS**

This is in response to the Office Action mailed on July 26, 2005. Claims 2-5, 8-31, and 34-37 are pending in the application. Claims 2, 5, 11, 34, 36 and 37 have been amended. Support for the amendments can be found throughout the application, e.g., ¶¶ 0002, 0003, 0007, 0013, 0023, 0043, 0051, and 0053-0060. No new matter is included in these amendments.

Reconsideration of the above-referenced patent application in view of the amended claims and following remarks is respectfully requested.

### **Claim Objections**

The Examiner objects to claim 1 because "tin a" should read "a tin." Applicants believe the Examiner objects to claim 2, as claim 1 was previously cancelled. Claim 2 has been amended to change "tin a" to "a tin." Accordingly, Applicants respectfully request that this ground of objection be withdrawn.

### **Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 1-5, 8-31 and 34-37 as indefinite under 35 U.S.C. § 112, second paragraph because the claims directed to a tin mesoporphyrin complexed with at least one amino acid "would not direct one skilled in the art as to where on the tin mesoporphyrin the amino acid complexed." Again, Applicants believe the Examiner has rejected claim 2, rather than claim 1, under § 112, second paragraph. Applicants respectfully traverse this rejection.

The second paragraph of 35 U.S.C. § 112 states:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

According to MPEP § 2171, there are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Applicants respectfully submit that the claims are indeed definite and distinctly claim the subject matter they regard as their invention.

Regarding, indefiniteness, MPEP § 2173.02 states:

When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness.

The fact that a claim is broad does not make it indefinite. See In re Miller, 441 F.2d 689, 169 USPQ 597 (CCPA 1971) ("Breadth of a claim is not to be equated with indefiniteness"), quoted in MPEP § 2173.04. Instead, the Federal Circuit stated that the proper test for definiteness under § 112 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986), quoted in MPEP § 2173.03. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with § 112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by

§ 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent.

In this case, a skilled artisan would easily recognize that Applicants have invented and claimed a broad, but definite, class of compounds. The term "mesoporphyrin" means only one definite molecule, the term "amino acid" means one of twenty well-known molecules, the term "at least one" means "one or more", and the term "complex" means "an association of two or more molecular entities." Accordingly, a skilled artisan would recognize that the claim language means an association of tin mesoporphyrin with one or more amino acids, wherein the said amino acid or amino acids can be attached to any site on the mesoporphyrin molecule.

In addition to the argument that the claims directed to a tin mesoporphyrin complexed with at least one amino acid "would not direct one skilled in the art as to where on the tin mesoporphyrin the amino acid complexed" the Examiner states that:

it would be impossible to perform a meaningful and successful prior art search, as this class of compounds is very broad and to search all the compounds is very broad and to search all of the compounds of the class with an amino acid complexed at every site on the tin mesoporphyrin core would be impossible.

Clearly, the Examiner did not state that the application was so incomprehensible that a reasonable prior art search could not be made, and "very broad" does not equal "incomprehensible." Moreover, the Examiner has not objected to the application under 37 C.F.R. § 1.71 as required under MPEP § 702.01 if the disclosure is "so incomprehensible as to preclude a reasonable search of the prior art."

Applicants respectfully reiterate that breadth of the claim is not indefiniteness and that difficulties in conducting the prior art search do not constitute a proper ground for a rejection. However, in the interest of expediting prosecution, claims 2, 5 and 11 (and those dependent thereon) have been amended to recite that the mesoporphyrin/amino acid compound or complex is water soluble, thereby limiting the number of mesoporphyrin complexing sites to those that achieve this result. A person skilled in the field of the

invention would reasonably understand that the present invention claims water soluble tin mesoporphyrin compounds wherein a tin mesoporphyrin is complexed with an amino acid. The specification teaches how to complex tin mesoporphyrin compounds with amino acids and how to determine whether the complexed compound is water soluble. The amended claims clearly meet the requirements of 35 U.S.C. 112, second paragraph. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

The Examiner has also rejected claims 34 and 35 under 35 U.S.C. § 112, second paragraph because the claims are incomplete as a result of the term "medical condition" being indefinite. Claim 34 has been amended to recite that the medical condition is a "heme metabolism disorder." Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

#### **Claim Rejections – 35 U.S.C. § 103**

The Examiner has rejected claims 1-10, 22, 32-35, and 37 under 35 U.S.C. § 103(a) as obvious over Robinson, U.S. Pat. Pub. No. 2003/0100752 (hereinafter "Robinson"). The Examiner specifically refers to claim 1 of Robinson, which the Examiner believes allows for a possibility that R<sub>1</sub>-R<sub>12</sub> and M can be selected in a manner to comprise a tin mesoporphyrin and wherein an amino acid could be complexed at R<sub>3</sub>, R<sub>6</sub>, R<sub>9</sub> or R<sub>12</sub>. Again, Applicants believe the Examiner has rejected claim 2, rather than claim 1, under § 103. Applicants respectfully traverse this rejection.

Establishment of a *prima facie* case of obviousness of a species when the prior art teaches genus requires, among other things: 1) determine the scope and content of the prior art, and 2) establish whether a skilled artisan would be motivated to select the claimed species or subgenus.

In consideration of a prior art reference disclosing a genus, the Examiner must consider:

- 1) the structure of disclosed prior art and that of any expressly described species or subgenus within the genus;
- 2) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the

usefulness of the genus, and any problems alleged to be addressed by the genus;

- 3) the predictability of the technology; and
- 4) the number of species encompassed by the genus taking consideration all of the variables possible.

Robinson's application describes a broad genus of porphyrins linked to a complexed agent via amine, amide, ester, or ether bonds. Considering that there are multiple radical (R) groups, five complexing agents, multiple L elements and at least ten metal ions, this genus easily encompasses tens of thousands of species. There is no disclosure OR suggestion, either in Robinson or in the prior art in general, supporting the selection of the species claimed by applicants out of the genus disclosed by Robinson.

Furthermore, the properties of the different species in the genus claimed by Robinson are highly dependent on the peripheral groups and thus highly unpredictable. Robinson discloses that "small changes in the peripheral functionality can have pronounced effects on the biological efficacy of the molecules as does metal co-ordination to the compounds." Robinson, ¶ 169.

In contrast to the broad genus claims of Robinson, the present invention is drawn to a very specific class of compounds (mesoporphyrin/amino acid complexes) with a very specific biological efficacy (treatment of heme metabolism disorders). As such, Robinson's genus cannot render obvious the present invention. However, in the interest of expediting prosecution, claims 2, 5 and 34 (and those dependent thereon) have been amended to recite that the mesoporphyrin is not derivatized with a complexing agent prior to complexing with one or more amino acids. Support for this amendment can be found in the Examples, particularly paragraphs 0043 to 0060, where it is clear that the complexes of a tin mesoporphyrin and amino acids are formed without any complexing agent. See MPEP Section 2173.05(i).

Robinson clearly teaches only derivatized porphyrin molecules containing a complexing agent of general formula IIA, IIB, IIC, IID or IIE containing various metal ion equivalents for use in photodynamic therapy, MRI and radioimaging. Nowhere in

Robinson is there a teaching or suggestion of an underivatized mesoporphyrin complexed with one or more amino acids for use in treatment of heme metabolism disorders. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

**CONCLUSION**

In view of the foregoing remarks, the application is believed to be in condition for allowance, and early notice to this effect is earnestly solicited. If allowance of this application may be expedited by resolution of simple issues through a telephone conference, the Examiner is welcome to call the undersigned.

No fees are believed due at this time. If any fees in connection with this requested Amendment are due however, the Examiner is authorized to charge Deposit Account No. 50-3329.

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Respectfully submitted,

By 

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